

REMARKS

Reconsideration of this Application is respectfully requested. Upon entry of the foregoing amendments, claims 23-38 are pending in the application, with claims 23 and 37 being independent claims. Claims 1-22 have been canceled without prejudice or disclaimer. Support for the subject matter of the amended claims is contained in the application as originally filed. Because the foregoing changes introduce no new matter, their entry is respectfully requested.

Claim Objections

Applicants respectfully submit that the Examiner's objection to claim 38 has been overcome by the amendment thereof.

Rejections under 35 U.S.C. § 102 and 103***Claims 23-38***

The Examiner has rejected claims 23-38 under 35 U.S.C. § 102 and 103 as being anticipated by, or unpatentable over U.S. Patent No. 6,865,444 to Howard et al. ("Howard"), alone or in combination with U.S. Patent Application number 2003/0074223 A1 to Hickle et al. ("Hickle"). Howard and Hickle, taken individually or combined, fail to teach or suggest the device of the present invention as currently claimed, including a reservoir containing an *oral formulation* for a controlled drug or drug of abuse as is called for by amended claims 23 and 37.

Howard does not disclose such a device. Instead, Howard discloses a device that dispenses *transdermal dosage forms* placed *on the skin of the patient* for a prescribed period of time so that the medication can be absorbed through the skin and delivered to the patient. *See* Howard col. 1, lines 17-25. The entire teaching of Howard is directed to a device for dispensing *transdermal* dosage forms. There is no mention of using the invention in Howard for delivering an oral formulation for patient use. In fact, Howard actually teaches away from the present invention as currently claimed: Howard describes "inactivating agents" such as emetics that are included in the transdermal patch to *prevent* their use orally. *See* Howard, col. 6, lines 13-18.

Hickle likewise fails to disclose or suggest a device including a reservoir containing an oral formulation for a controlled drug or drug of abuse wherein the patient's access to the formulation is monitored in real time. Hickle instead is related to the tracking of medical products to ensure quality control. There is no mention in Hickle of the possibility of real-time monitoring of a patient's use of a controlled drug or drug abuse.

In contrast, the device of the present invention as currently claimed is directed to a device including a reservoir containing an *oral formulation* for a controlled drug or drug of abuse wherein the patient's access to the formulation is monitored in *real time*. Again, Howard does not disclose the use of an oral formulation and teaches away from oral formulations as stated above, and Hickle does not disclose the possibility of real-time monitoring of a patient's use of a controlled drug or drug abuse.

In addition, Applicants traverse the Examiner's obviousness rejection of claims 26, 27, 29 and 30. Although the Examiner has listed the *Graham v. John Deere* factual inquiries on page 4 of the Office Action, the Examiner has not articulated the differences between Howard and the claims at issue, nor has the Examiner resolved the level of ordinary skill in the pertinent art. "Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art." *See MPEP § 2141 III.* "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious." *Id.* Applicants respectfully submit that the Examiner has failed to articulate any reasons why the claimed invention would have been obvious, and has also failed to set forth the *Graham v. John Deere* factual inquiries necessary for presenting a *prima facie* case of obviousness.

For at least these reasons, Applicant respectfully submits that Howard and Hickle, taken individually or combined, do not anticipate or render obvious independent claims 23 and 37. Applicant submits that claims 24-35 which depend from claim 23, and claim 38 which depends from claim 37, are allowable over the cited art for at least the same reasons noted above.

CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided below.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extension of time or additional claims, and/or credit any overpayment to Deposit Account No. 50-0310 (Order No. 187287/US).

Prompt and favorable consideration of this Amendment and Response is respectfully requested.

Respectfully submitted,

By:


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